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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,876	12/12/2003	Howard T. Bellin	2003-2090.CON	1026
23165	7590	11/18/2005	EXAMINER	
ROBERT J JACOBSON PA			SNOW, BRUCE EDWARD	
650 BRIMHALL STREET SOUTH			ART UNIT	
ST PAUL, MN 551161511			PAPER NUMBER	

3738

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/734,876

Applicant(s)

BELLIN ET AL.

Examiner

Bruce E. Snow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21, 23, 26, 28-33 and 35-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21, 23, 26, 28-33, 35-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Arguments*

Applicant's amendment filed September 8, 2005 has been fully considered.

Applicant states, "*Applicant appreciates the difference pointed out by the Examiner on page 2 of the Final Rejection of April 8, 2005*" and acknowledges that the Examiner cannot patentable differentiate the final device of at least McGahn et al and that of applicant due to the method of production. The Examiner notes MPEP 2113 which states:

*"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."*

Applicant then concludes, "*Applicant has taken such a difference identified by the Patent Office and has placed such into each independent claim in the case*" and now assumable believes the claims are allowable. The Examiner strongly emphasizes his position that "the Examiner **cannot** differential between McGahn et al" and applicant's device. Applicant has added the limitation "*with the envelope being made by a process comprising the steps of submerging a mandrel to pick up a first envelope-layer over a first portion of the mandrel, then again submerging said mandrel to pick-up a second envelope layer over a second portion of the mandrel, and then curing the envelope layers*". The Examiner notes that element envelope 12a is taught being formed in a mold and not by subsequent layers cured together, however, the resulting final product

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is the same. In a second interpretation, McGahn et al teaches a construction from five separate pieces. It is the Examiner's position that the separate silicone pieces cemented together with silicone to form a final product wherein the Examiner cannot differentiate final products of applicant and McGahn et al. Similar for Prescott and Baker.

The Examiner notes applicant's side-to-side comparison of the claim sets but they are not the same claims. For example, in comparing claim 1 of U.S. Patent No. 6,692,527 to current claim 21, applicant has failed to incorporate a major limitation. The limitation "wherein the envelope apart from said patch is one-piece" distinguished over McGahn et al because patch is needed to form an envelope with a thicker side with a relatively rough surface.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 23, 26, 28-33, 35-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The new limitation, as follows, added to all independent claims is new matter:  
*“with the envelope being made by a process comprising the steps of submerging a mandrel to pick up a first envelope-layer over a first portion of the mandrel, then again submerging said mandrel to pick-up a second envelope layer over a second portion of the mandrel, and then curing the envelope layers”.*

Originally filed claim 18 of 09/452,656 wherein applicant indicated support:

18. A method of making an envelope for a breast implant, comprising the steps of
- a) selecting a mandrel;
  - b) selecting a dispersion into which the mandrel is dipped;
  - c) fully submerging the mandrel in the dispersion such that an envelope is formed, withdrawing the mandrel from the dispersion and thereby picking up a first envelope layer on the mandrel, and permitting the first envelope layer to at least partially stabilize; and
  - d) partially submerging the mandrel in the dispersion such that a portion of the mandrel remains exposed to the atmosphere, withdrawing the mandrel from the dispersion and thereby picking up a second envelope layer on the mandrel and permitting the second envelope layer to at least partially stabilize, whereby an envelope coating of a first thickness is disposed over one portion of the mandrel and whereby an envelope coating of a second thickness is disposed over another portion of the mandrel.

Applicant's claim language describing a first portion is broader than “fully submerging the mandrel” which is the entire surface. Also, the second portion is a part of the first portion and not exclusive portions as written, thus forming a second layer over the first layer.

Note, claim 33 is a "method of minimizing rotation of an implant" and not a method of forming an implant. Therefore, the claim language directed to the steps of forming the implant are interpreted as they would in a device claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 23, 26, 28-33, 35-46 (all claims) are rejected under 35 U.S.C. 102(b) as being anticipated by McGhan et al (3,852,832).

McGhan et al teaches a breast implant comprising a fillable "envelope" having one side having a relatively smooth surface and another side (comprising 12a, 12d, and 37) having a relatively rough surface to allow for tissue ingrowth. The implant, as clearly

shown in figures 3-4, has a relatively thicker side comprising said relatively rough surface.

Note column 2, lines 53 et seq., teaching the implant is formed to a mold and then stripped leaving an aperture opening which is later closed by a closer 12d, interpreted as a patch.

Regarding claims 42-46, McGhan et al teaches the thickness of sheet 37 which is the only thickness over the aperture 12c, and is approximately 20/1000 inches thick which is interpreted as being about 18/1000 inches thick. From the drawings, the smooth surface is shown as being thinner and is interpreted as being within the claimed range.

It is the Examiner's position that the separate pieces cemented together form a final product that is "one-piece".

Additionally, applicant has added the language wherein the envelope is sealable after being filled with said fluid which is merely functional language. The implant of McGahn et al is fully capable of being sealed by a patch after being filled, etc.; note that the implant has a valve 15 which does seal after being filled.

Claims 21, 23, 26, 28-33, 35-46 (all claims) are rejected under 35 U.S.C. 102(b) as being anticipated by Prescott (5,522,896).

Referring to figure 1B, Prescott teaches a breast implant comprising a fillable "envelope" having a relatively smooth anterior surface and a thicker posterior side comprising elements 4 and 6. Prescott teaches an additionally layer/coating 4 on a breast prosthesis:

*"The prosthesis of the present invention can also comprise a base material of predetermined shape, e.g., a conventional prosthetic device, and a layer of elastomeric material provided on the base material, wherein the layer of elastomeric material has distributed therein or provided thereon bio-active ceramic or glass particles (column 5, lines 34-39)."*

Inherently, a conventional prosthetic with an additionally coating, such as the breast implant such in figure 1B, would produce a thicker posterior side relative to the anterior side. It is noted that Prescott teaches the coating to increase tissue adhesion; see at least column 1, lines 29-38. The posterior surface with coating is relatively rough when compared with the anterior surface without a coating. The implant is fully capable of being sealable after being filled.

Claims 28, 30, 32, 39, 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Baker (5,026,394).

Baker teaches a breast implant comprising a fillable "envelope" having a relatively smooth anterior surface and a thicker posterior side 20, 14. Said implant envelope is sealed, and wherein the envelope apart from said patch 34, 72 is one piece.

Note column 6, lines 65-66, "the shell component and the reinforcement member can be formed as an integral unit."

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

In the alternative, claims 42-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGhan et al (3,852,832) or Precott (5,522,896).

McGhan et al discloses the invention as described above including the thickness as described above. Lacking any criticality in the specification, the use of the claimed thicknesses lacks criticality in the specification and solves no stated problem and would have been an obvious matter of design choice within the skill of the art. Additionally, it would have been obvious to one having ordinary skill in the art to adjust the thickness of both sides of the implant to adjust flexibility and/or increase strength.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bes

A handwritten signature in black ink, appearing to read 'BSN', with a stylized, looping flourish extending from the end.

**BRUCE SNOW**  
PRIMARY EXAMINER